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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,792	10/24/2003	Phillip E. Gesotti	105.007US01	3594

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EXAMINER

KAHELIN, MICHAEL WILLIAM

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3762

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/693,792	Applicant(s) GESOTTI, PHILLIP E.	
	Examiner Michael Kahelin	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-102 is/are pending in the application.
- 4a) Of the above claim(s) 24-89 and 91-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-23 and 90 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070306</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/6/2007 have been fully considered but they are not persuasive. Applicant argued that Larson fails to disclose a "plurality of stimulation prompts [that] are not synchronized with the patient's gait" because the "standing" configuration of Larson is not stimulation for "a patient's gait" and the body's inherent time lag does not mean that the gait response is not synchronous, but only that Larson uses software time lags to "avoid unstable oscillation". Applicant further cited passages from the instant Application's specification that allegedly diverge from Larson's invention.
2. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "The contraction of the muscle is not coincident with the prompt" and "patients perform better when they do not attempt to synchronize with the cues") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).
3. In response to applicant's argument that "standing" is not a "patient's gait", the recitation "improving a patient's gait" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a

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structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Further, the claim is a “comprising” claim. Therefore, any additional steps (such as standing before walking) disclosed by Larson are considered to be part of the broad method of “improving a patient’s gait”. It is certainly required that a patient is standing before walking takes place. As such, the act of standing contributes to the method of “improving gait” for a patient that cannot otherwise stand or walk.

4. In response to the argument that the body’s inherent time lag does not mean that the gait response is not synchronous, but that Larson only discloses software time lags to “avoid unstable oscillation”; the fact that Larson utilizes software time lags when varying different variables is irrelevant to the fact that there is still a lag between the stimulation prompts and patient response. As Larson discloses a delay between prompts and response, the prompts and response (gait) are not synchronous.

Regardless of whether the response follows or occurs at the same frequency (i.e. if the stimulation controls the duration of the steps) as the stimulation and because there exists a phase shift (the 100 millisecond delay) between the stimulation and response, the stimulation and response do not occur at the same time (synchronously).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 9-13, 16, 18-21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Larson et al. (US 4,697,808, hereinafter "Larson").

7. In regards to claims 1 and 3 Larson discloses a method for improving a patient's gait by utilizing the disclosed apparatus and comprises producing a plurality of stimulation prompts at a plurality of points using a plurality of channels placed symmetrically on each leg (Figs. 13 and 14); applying the prompts in a periodic fashion (col. 7, line 41); wherein the prompts are not synchronized with the person's gait (i.e. for standing; col. 5, line 44); each channel is associated with an electrode (Figs. 13 and 14); and a return electrode is inherently activated whenever a stimulation channel is active because a return electrode is required to generate a stimulation voltage. Please note that Examiner is interpreting the "standing" as being "not synchronized with the patient's gait". Further, Larson discloses that "the body has an inherent time lag of about 100 milliseconds in responding to stimulation", which means that the gait response is not synchronous with stimulation.

8. In regards to claims 9-13, 16, 18, and 19, each of three stimulation channels is associated with a cue clock that activate stimulation electrodes during a cue interval on

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one leg (col. 7, line 45). Further, three additional channels are activated during the same portion of opposite cue intervals (i.e. 180 degrees out-of-phase; col. 7, line 53).

9. In regards to claims 20, 21, and 23, the pulse width is 300 microseconds, which is approximately 400 microseconds (col. 7, line 52); the pulses are biphasic (col. 7, line 58); and the stimulation current is approximately 10mA (col. 8, line 31).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Larson. Larson discloses the essential features of the claimed invention, including ramping the pulse (col. 6, line 11) to account for the human body's response time lag and adjusting the period of the pulse (col. 7, line 8), but does not explicitly disclose that this adjustment is linear. It is well known in the art to adjust variables linearly to reflect the linearity of many natural phenomena, apply a smooth transition between stimulation values, and minimize computational requirements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the pulse period as disclosed by Larson in a linear manner to reflect the linearity of many natural phenomena, apply a smooth transition between stimulation values, and minimize computational requirements.

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12. Claims 2, 7, 8, 14, 15, 17, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larson.

13. In regards to claims 2, 7, 8 and 22, Larson discloses the essential features of the claimed invention except for stimulating at a period of 14 milliseconds; stimulating the anterior tibial muscle, gastrocnemius, and rectus femoris; or time division multiplexing stimulation pulses. It is well known in the art to stimulate with a period of 14 milliseconds to ensure patient comfort and avoid cutaneous burning; to stimulate the anterior tibial muscle, gastrocnemius, and rectus femoris to target the main muscles responsible for walking; and to stimulate using time division multiplexing to allow a single processing circuit to apply several signals. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Larson's invention with a pulse period of 14 milliseconds to ensure patient comfort and avoid cutaneous burning; to stimulate the anterior tibial muscle, gastrocnemius, and rectus femoris to target the main muscles responsible for walking; and to stimulate using time division multiplexing to allow a single processing circuit to apply several signals.

14. In regards to claims 14, 15, and 17, Larson discloses the claimed invention but does not disclose expressly the cue intervals of 0.4 seconds and that the third cue clock is active during the second quarter of the first cue interval. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stimulation parameters as taught by Larson with the claimed stimulation parameters because applicant has not disclosed that the stimulation parameters provides an

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advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Larson's stimulation device because both devices have timing intervals that facilitate smooth walking. Therefore, it would have been an obvious matter of design choice to modify Larson's stimulation parameters to obtain the invention as specified in the claims.

Allowable Subject Matter

15. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GEORGE R. EVANISKO
PRIMARY EXAMINER

6/12/07

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